

Exhibit 2

Historical Contribution

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The Interconnected Histories of Endocrinology and Eligibility in Women's Sport

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Abstract

This report illustrates the links between history, sport, endocrinology, and genetics to show the ways in which historical context is key to understanding the current conversations and controversies about who may compete in the female category in elite sport. The International Association of Athletics Federations (IAAF) introduced hyperandrogenemia regulations for women's competitions in 2011, followed by the International Olympic Committee (IOC) for the 2012 Olympics. The policies concern female athletes who naturally produce higher-than-average levels of testosterone and want to compete in the women's category. Hyperandrogenemia guidelines are the current effort in a long series of attempts to determine women's eligibility scientifically. Scientific endeavors to control who may participate as a woman illustrate the impossibility of neatly classifying competitors by sex and discriminate against women with differences of sex development (also called intersex by some).

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Introduction

The International Association of Athletics Federations (IAAF) introduced its hyperandrogenemia regulations in 2011, which concerned athletes designated female at birth who naturally produce higher-than-average levels of testosterone and want to compete in the women's category of sport. According to the IAAF, testosterone promotes athletic ability and hyperandrogenemic women possess an unfair advantage in sport due to this increased level [1]. The organization established a 10 nmol/L cutoff for participants in the women's division, which the International Olympic Committee (IOC) adopted for the 2012 London Olympics. Critics of the policy argue that testosterone is only one factor of many involved in sporting prowess; moreover, naturally produced testosterone is a biological advantage akin to many genetic advantages, for example, tall height [2–5]. Opponents also likened the policy to previous forms of sex testing [6]. The IAAF first introduced compulsory visual inspections in 1966, followed by a buccal smear test in 1967 [7]. The IOC implemented mandatory chromosomal screenings in 1968 [8, 9]. A recent update to this policy is noted below.

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This review illustrates the interconnections of history, sport, endocrinology, and genetics to show the ways in which historical context is key to understanding the current conversations and controversies about who may compete as a woman in elite sport. The IAAF's and IOC's hyperandrogenemia policies are one in a series of efforts to determine women's eligibility *scientifically*. Both organizations incorporated different techniques to distinguish men and women; however, the attempts showed the impossibility of neatly classifying competitors through scientific means and discriminated against women with differences of sex development (DSD). Because most testing occurred in elite track and field competitions and the Olympics, we focus on the IAAF's and IOC's verification practices. Moreover, the IAAF and IOC historically maintained a western bias in organization and membership; therefore, we highlight western sport history, athletes, organizations, and countries. Finally, only athletes whose medical records have been *verified and published* are discussed. We do not discuss situations based on unconfirmed reports and rumor.

Sex Testing in Elite Sport

Western sport developed in the mid-1800s. Before that, physical pursuits were local, not record-oriented, and not standardized [10]. Western sport also developed as a way for men to demonstrate their masculinity [11–15]. Wealthy men organized amateur leagues and decried commercialization and professionalization [10–12]. Women therefore remained sidelined or limited to purposive exercises like calisthenics [11, 14, 16]. The IOC, formed in 1894 and comprised of men from western countries, served as one of the first international multi-sport organizations with longevity, stability, and influence [17].

Under the authority of founder Pierre de Coubertin, the IOC organized the first Olympic Games in 1896. During the 1896 Athens Games, 241 men from 14 countries competed in athletics (track and field), cycling, fencing, gymnastics, shooting, swimming, tennis, weightlifting, and wrestling. The IOC barred women from competition [17, 18]. During the 1900 Parisian Games, women did participate, albeit only in croquet, golf, and tennis, activities deemed socially appropriate [19–22]. Upper-class, white women participated in these events, which did not require bodily contact, in full-skirted outfits [11, 14, 21]. Women remained barred from most events, notably track and field, for the first part of the twentieth century.

Track and field was the most popular and prestigious of the Olympic sports and considered the most masculine by practitioners and the public alike. Sport organizers believed track and field was too strenuous and grueling for women [22–24]. Because women were excluded from most Olympic events, Alice Milliat, founder and president of the Fédération Sportive Féminine Internationale (FSFI), organized the Women's Olympic Games in 1921, the first major international track and field forum for women [11, 25]. The IAAF and IOC agreed to accept female competitors in track and field if Milliat agreed to drop the word Olympics from her event, but the IOC agreed to add women to 5 events – half of what was originally promised to Milliat [11, 25].

Women who competed in athletics faced reproach for being masculine [11, 26]. White, middle-class women avoided the sport because of the stigma, leaving a vacuum that white, working-class women and women of color filled. This provided new opportunities for these women, but it also reaffirmed the idea of track and field as masculine and inappropriate in the context of western societal norms. It additionally reinforced stereotypes of black women as less feminine than white women [11, 14, 27]. Track and field female athletes thus experienced the most criticism and scrutiny [28].

When women started to excel in track and field, questions surfaced about the masculinizing effects of the sport, which eventually convinced the IAAF and IOC to introduce sex testing. In the 1936 Olympics, 19-year-old American athlete Helen Stephens underwent the first publicized sex test of the modern Olympics. She defeated previous record-holder Stella Walsh (discussed below) in the 100-m race, in a record-setting fashion. Because people did not believe a woman could run that fast, they called upon officials to verify her sex [29]. Similar to the dominant viewpoint of many western countries, Nazi ideology promoted women as mothers and homemakers but also recognized that medals earned by female athletes increased the status of the nation [30]. Either the American Olympic Committee or Berlin officials conducted a physical examination, which Stephens "passed" [29, 31].

Stephens' plight – along with the muscular appearances and successes of Soviet athletes in the 1950s and 1960s – convinced the IAAF and IOC to introduce a more systematic approach to verifying sex [32–34]. After a brief hiatus due to World War II, the IAAF required medical documentation of sex for all female competitors from physicians in 1946. The IOC followed suit in 1948 [35]. The fear that this opened the door for fraudulence against

the backdrop of the Cold War led the two organizations to introduce mandatory, on-site testing.

The IAAF required physical examinations starting in 1966 [6]. Testing first occurred at the British Empire and Commonwealth Games, in Kingston, Jamaica. Some athletes remembered a manual component to this visual check. British athlete Mary Peters described it as a “grop” [36] and Canadian runner Abby Hoffman recalled that in a 1992 interview with the *Globe and Mail*, “they may have laid a hand on the genital area to make sure there were no hidden genitals.” At the 1966 European Athletics Championships, 3 female doctors visually inspected all 243 female participants [37]. The “nude parade” continued at the 1966 Asian Games and 1967 Pan American Games [38].

Athletes’ disdain of the “nude parades” and the belief that scientific techniques could conclusively determine sex led the IAAF to introduce a chromatin test for the 1967 European Cup Track and Field Event in Kiev, Soviet Union. The federation removed any athlete whose buccal smear test did not show the Barr body, indicative of the second (inactive) X chromosome [38]. According to the French doctor Jacques Thiebault, this type of testing helped quiet the rumors about the “so-called females who are as strong as oxen” [39]. The IOC therefore introduced the buccal smear test at the 1968 Grenoble Winter Olympics on a limited basis. Although the test did not uncover any male imposters, the IOC mandated all female Olympians to undergo the buccal smear test at the 1968 Mexico City Summer Olympics [39].

The IAAF continued mandatory, on-site testing until 1992 and the IOC until 1999. During the 30 years of sex testing, several athletes quietly retired from sport due to the policy. According to Mexican gynecologist and IOC Medical Commission member Eduardo Hay, from 1968 to 1980, approximately a dozen athletes preferred to withdraw from sport rather than undergo additional testing [40]. Hay also noted in 1988 that the testing had never uncovered a man falsely posing as a woman [41]. The IAAF and IOC kept the names of athletes who “failed” confidential; therefore, the number of women removed from sport at the international level remains unknown. Accounts from medical practitioners suggest that the individuals disqualified from sport (discussed below) were not male imposters, but women with DSD [42, 43]. Geneticist Albert de la Chapelle was one of the first to argue that the use of the Barr body test in sport was unethical and discriminated against women with DSD [42].

Athletes Removed from Sport through Sex Testing

The first athletes who experienced gender-based scrutiny were those who underwent sex reassignment surgery following their athletic careers. We will follow GLAAD’s (formerly known as the Gay & Lesbian Alliance Against Defamation, but changed in 2013 due to the organization’s inclusion of bisexual and transgender issues) and the Human Rights Campaign (HRC) guidelines when discussing transgender athletes, particularly with regard to pronouns. GLAAD and the HRC suggest that because an individual’s transition is an ongoing process of affirming one’s gender identity, and not necessarily a turning point that centers medical interventions, it is best to use pronouns consistent with the way the person identified and lived [44, 45].

British athlete Mary Weston competed as a woman and won the British Women’s Amateur Athletic Association (WAAA) shot-put title in 1925 and 1928 and finished first in the 1929 WAAA Championships in the discus, javelin, and shot-put. Weston was designated female at birth and lived as a woman until he started studying to become a masseur. As part of the educational requirements, he completed anatomy courses, which led him to question his sex. He eventually underwent “a series of operations” and re-registered as male in 1936 [46]. Reports indicate he later fathered 3 children [35]. Similarly, Zdeňka Koubková was identified female at birth and competed for Czechoslovakia as a woman, breaking the world record in the 800-m race. Appearance-based suspicions convinced the Fédération Sportive Féminine Internationale to conduct a physical examination. The discovery of ambiguous genitalia led them to strip Koubková of the previous victories. Koubková opted to undergo sex reassignment surgery and changed his name to Zdenek Koubek [47]. Neither Weston nor Koubek competed as frauds; both were identified female at birth, raised as girls, and believed themselves to be women. Rather than examples of gender imposters, Weston and Koubek were likely individuals with DSD.

Heinrich Ratjen is another example of an athlete who was identified female at birth but later lived as a man. Ratjen competed as Dora, his given birth name, in the 1936 Olympics, finishing fourth in the high jump. Although popular lore suggests the Nazis forced his faux participation, medical records indicate he grew up female. German journalist and editor of *Spiegel Online*, a German website, accessed and analyzed previously unexplored police files. The documents suggest that the midwife present at his birth first declared Ratjen a boy, before

asserting the child was female. The midwife concluded it was best to raise Ratjen female, which the parents did. When Ratjen was 9 months old, his father asked the doctor to inspect the child's genitalia. The doctor noted that Ratjen had abnormal genitalia but told the father to "Let it be. You can't do anything about it anyway" [35, 48]. In 1938, Ratjen was arrested for "cross dressing" while aboard a German train. The public prosecutor explained that "fraud cannot be deemed to have taken place. After all, Dora had never been told he was a man" [48]. Ratjen returned his medals and lived the rest of his life as a man, Heinrich.

Athletes with later verified DSD also experienced criticism and expulsion from sport. In 1949, 22-year-old Dutch athlete Foekje Dillema defeated Holland's "Flying Housewife," Fanny Blankers-Koen. One year later, Dillema was banned from competition for either refusing to undergo a sex test or "failing" it. The IAAF excluded her from athletics and erased her national record in the 200-m race. Dillema was designated female at birth and lived as a woman. It is reported that her family did not suspect she had DSD, despite having seen her without clothing. A posthumous forensic test suggested she had 46XX/46XY chromosomal mosaicism [49].

The Polish runner Ewa Kłobukowska had a similar experience. Just before her twentieth birthday, she passed the IAAF's mandatory visual inspection during the 1966 European Championships, then earned gold in the 100-m race, silver in the 200-m race, and another gold in the 4 × 100-m relay. However, during the 1967 European Cup, the IAAF disqualified her and revoked her medals for "failing" the newly introduced buccal smear test. According to the IAAF's account, she had "one chromosome too many." Reports indicate she had genetic mosaicism, XX/XXY; however, the percentage of each karyotype was not noted [38]. Despite the Polish Olympic Committee president's concerns that the buccal smear test unfairly and arbitrarily designated sex, many other sports officials viewed Kłobukowska's case as justification for continued testing.

After the IOC followed the IAAF's lead and implemented the buccal smear test in 1968, Olympians with DSD withdrew from sport. Prior to the 1968 Grenoble Winter Olympics, the Austrian ski team members all underwent the check to ensure they would pass at the Olympics. Nineteen-year-old team member Erika Schinegger was informed she possessed internal male sex organs. Schinegger underwent sex reassignment surgery and returned to competition as Erik [37].

According to sports officials, the removal of athletes with DSD permitted a level playing field [9]; therefore,

both the IAAF and IOC continued the practice for several decades. The death of Olympian Stella Walsh (see 1936 Olympics, above) seemingly added additional support for the practice. In 1980, Walsh was murdered in a convenience store parking lot. The autopsy revealed that she had an abnormal urethra, no uterus, and underdeveloped testes [50]. A buccal smear test also revealed the presence of both XX and XY sex chromosomes. Although the coroner cautioned against making misleading statements about Walsh's sex, the IOC interpreted the autopsy results as evidence for the need for sex testing to determine the eligibility to compete as a woman. The IAAF and IOC continued to test those who considered themselves as women.

The removal of a woman with androgen insensitivity syndrome from sport eventually caused the two sports organizations to halt sex testing. During the 1983 World Track and Field Championships, 22-year-old Spanish hurdler María José Martínez Patiño received her "femininity certificate," the documentation provided to women by the IAAF or IOC upon a successful sex test. Two years later during the World University Games, however, she forgot her "fem card" and had to retake the buccal smear test. This time, she "failed." The team doctor suggested she quietly retire from sport. Patiño refused and competed in the 1986 Spanish National Games. Her victory sparked international outcry and Spanish sport officials barred her from competition, erased her records, and revoked her scholarship [51]. Her refusal to withdraw from sport silently brought attention to the IAAF's and IOC's sex testing practices. As a result, many medical practitioners protested the singular use of the buccal smear test to verify sex. The widespread objections to sex testing led the IAAF to terminate the practice in 1992 and the IOC in 1999. Yet the halting of testing proved brief. In 2011, the IAAF and IOC introduced a new eligibility parameter via a hyperandrogenemia policy.

Athletes and Hyperandrogenemia

The IAAF outlined a hyperandrogenemia policy in 2011, which the IOC adopted for the 2012 London Olympics. Hyperandrogenemia may be expressed in a number of ways. The first, and perhaps most global, would be above that concentration at +2 SD (or another arbitrary number) from the mean of the population of interest and determined with a specific, validated assay. Alternatively, one would gather women with a specific diagnosis, for example, those with the polycystic ovary syndrome

(PCOS) and note a population mean within the hyperandrogenemic range. Another would be to note that level at the lowest limit of normal for adult men as has been done by the IAAF and IOC [1, 52], under the assumption that some of the differences in performance between female and male athletes are due to androgen levels (testosterone, free testosterone, or another potent androgen at the androgen receptor). Initially the lower limit of T concentration for a male ~10 nmol/L (total T) was chosen. This concentration is approximately 5 times the upper limit of normal for adult women in the early follicular phase of the menstrual cycle [53].

Reproductive dysfunction is quite common among elite female athletes not receiving oral contraceptive pills. There is the well-described female athlete triad (also known as relative energy deficit in sport) [54] of associated eating disorders, amenorrhea/oligomenorrhea, and osteopenia from low total energy (calories) availability. Most such women who compete in sports such as distance running, diving, and figure skating have hypogonadotropic hypogonadism with low plasma concentrations of sex steroids, gonadotropins, insulin, IGF-I and increased levels of IGFBP-1 and cortisol [53–56].

Other athletes not in the catabolic state, in the sense of negative energy balance, may fit the criteria for PCOS or another variant of hyperandrogenemia. Hagmar et al. [57] noted enhanced diurnal secretion of testosterone and LH, low circulating levels of SHBG and a high frequency of polycystic ovarian morphology on ultrasound examination. A subset of Olympic athletes had anabolic body compositions and hormone profiles consistent with those in women with PCOS: an increased ratio of LH to FSH and higher T levels [57]. These findings were highest among power athletes such as runners and throwers and least frequent in technical sport such as archers and shooters. The bone mineral density as well as biomarkers of energy availability were within the normal limits and differ markedly from those athletes with the female athlete triad.

Athletes with other reasons for hyperandrogenemia, for example some with 46,XY DSD, had these findings to a greater degree. No athletes with known classical or non-classical congenital adrenal hyperplasia were tested, but would likely have some of these findings, especially if they were undertreated with glucocorticoids.

Elite female athletes differ from normal populations with slightly higher circulating concentrations of T and free T (and perhaps other potent androgens) even in the absence of doping. The mean concentrations do not differ greatly, but there are significant outliers. In anticipation

of using the athlete biological passport, the longitudinal profile and all other relevant information including training, competitions and information derived from investigations (in this case relevant to anabolic steroids) [58], as an alternative to drug testing, Bermon et al. evaluated T and calculated free T concentrations in a large population of high level female athletes. Of 849 sampled, 5 were deleted because of suspected and later confirmed doping and another 5 were deleted because of known hyperandrogenemia due to 46,XY DSD. Nine of the remaining 839 athletes had T concentration above 3 nmol/L; all had oligo/amenorrhea [59]. Testosterone levels differed among the various types of athletic events – throwers, sprinters and to a lesser extent, jumpers had higher T levels than the distance runners, in agreement with the anabolic (with reference to energy balance) phenotype discussed by Hagmar et al. [57]. The T concentration had a geometric mean of 1.78 nmol/L, compared to a similar normal population (1.6; 95% CI 1.046–1.72), but a mean of 2.68 nmol/L because of a few, very significant outliers.

In 2011 the IAAF, and in 2012 the IOC recommended governing the eligibility of women with hyperandrogenemia to compete as women [1]. The 10 nmol/L concentration was chosen in the absence at that time of normative data for athletes. The highest concentration permissible was chosen as ~10 nmol/L, the lowest limit in normal men, but not necessarily athletes. Subsequent data revealed a number of male athletes well below the 10 nmol/L level.

With the policy in place for the 2012 London Olympics, 4 women athletes, all 21-year-old or younger from “rural or mountainous regions of developing countries,” were identified as being hyperandrogenemic [60]. The IOC barred all 4 from competing and took them to France for evaluation and possible treatment [60]. While in France, the athletes underwent genital reconstructive surgery including clitoral recession and gonadectomy that “ensured” their future participation in sport, competing within the female category. Those opposed to the hyperandrogenemia policy questioned the consent of the athletes and the ethics of performing surgery for eligibility in sport.

The IAAF and IOC maintained the policy. Before the 2014 Commonwealth Games, the Sports Authority of India (SAI) pulled Indian sprinter Dutee Chand aside for medical testing. Just days before the start of the competition, SAI deemed Chand ineligible [61]. Officials offered her assistance with the required medical treatment. She refused and protested the hyperandrogenemia policy at the Court of Arbitration for Sport (CAS). The CAS panel

accepted the IAAF's position that testosterone is a key factor in increased lean body mass in males, and that increased lean body mass confers a competitive advantage in sport. The panel therefore accepted that testosterone is the best indicator of performance differences between men and women. However, the panel found that there was insufficient evidence about the *degree* of quantitative advantage female athletes with hyperandrogenemia enjoy over female athletes without hyperandrogenemia. The CAS panel suspended the policy for 2 years. The ban would be in place until (within these 2 years) there were data presented to establish both the degree of competitive advantage conferred by endogenous testosterone and if it neared the 12% difference common between male and female athletic performances to justify excluding women with hyperandrogenemia from the women's category of sport [61]. The CAS gave the IAAF 6 additional months for the evaluation of the data.

The IAAF issued new "Eligibility Regulations for Female Classification" (Athlete with Differences of Sexual Development, DSD) in April 2018. The new regulations apply only to female athletes who compete in events from 400 m to the mile, including hurdles races, 800-m, 1,500-m, and 1-mile races, and combined events over the same distances [62]. Any athlete with a DSD and levels of circulating total testosterone above 5 nmol/L and who is sensitive to the biological effects of testosterone must meet the following criteria:

1. Recognized by law as either female or intersex (or equivalent).
2. Reduce the circulating level of testosterone to below 5 nmol/L for at least 6 months.
3. Maintain the circulating testosterone level below 5 nmol/L continuously [63].

The effective date is November 1, 2018 to permit the 6-month period of lowered testosterone levels.

The revised regulations are based largely upon a 2017 study that evaluated the influence of testosterone levels on athletic performance [64]. Bermon and Garnier [64] analyzed the performances of women at the 2011 and 2013 IAAF World Championships. They divided the female competitors into 3 tertiles based on their free testosterone concentrations – low, medium, and high – then compared the high free testosterone tertile performances against the low free testosterone tertile performances. The study found statistically significant advantages in 5 events: 400 m (2.73%), 400-m hurdles (2.78%), 800 m (1.78%), hammer throw (4.53%), and pole vault (2.94%). These differences are well below the overall 10–12% difference between men and women in the same events.

These new regulations remain problematic and seemingly do not restrict field athletes, for example, shot-putters or pole vaulters. Some have critiqued the study's methodology, highly selective sample size (which seemingly included female athletes who had doped), and statistical processing [65–67]. Chand is unable to challenge the policy as she competes in the 100- and 200-m races, events not included in the new rules. South African runner Caster Semenya announced in June 2018 that she will challenge the IAAF's policy to the CAS.

Non-DSD female athletes' responses to the IAAF's and IOC's hyperandrogenemia policies have been varied. After finishing sixth in the 800-m race at the Rio Olympics, British runner Lynsey Sharp criticized the CAS panel's suspension of the IAAF's 2011 policy. Law professor and former elite runner Doriane Lambelet Coleman argued in favor of the testosterone-based rules as a way to protect the boundaries of women's sport [68, 69]. In contrast, 60 female athletes, including track and field Olympians Madeleine Pape and Suzy Favor Hamilton, joined the US-based Women's Sport Foundation and Athlete Ally in calling for the IAAF to rescind the new regulations. They argued that "no woman should be required to change her body to compete in women's sport" [70].

Conclusion

The history of the IAAF's and IOC's sex testing demonstrates links among sex, gender, genetics, endocrinology, and sport. Against the advice of endocrinologists and geneticists, sport officials relied upon "scientific" methods to help verify female athletes' sex. However, rather than expose male imposters, sex testing demonstrated the impossibility of scientifically determining competitors' sex. The IAAF's and IOC's reliance on the buccal smear test discriminated against women with DSD. Sex tests did not identify male masqueraders, but impacted individuals who lived their entire lives and competed as women. Moreover, the practice ended up impacting women from less affluent countries that lacked the medical technologies needed to detect DSD. The historical examples of women removed from sport provide important context for the current debates regarding who can compete as women in elite sport.

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